

Remarks:

Applicants have read and considered the Office Action dated July 9, 2004 and the references cited therein. Claims 41, 51, 52, 68, 70, 72, 74-76 and 80 have been amended. Claims 41 to 80 remain pending in the application. Reconsideration of this Application and entry of the foregoing amendments are requested.

In the Office Action, claims 41, 42, 44-65, 70, 71, 79, and 80 were rejected under “obviousness-type double patenting” in view of U.S. Patent 6,762,160 (Barbeau *et al.*). Claims 41-43, 45, and 64-68 were rejected under 35 U.S.C. § 102(b) as being anticipated by Goldemberg *et al.* (US 4,666,708). Claims 41, 58, 60, 64 and 68 were rejected under 35 U.S.C. § 102(e) as being anticipated by Tuompo *et al.* (US 5,910,420). Claims 41-43, 45, 47-71, 74, 79 and 80 were rejected under 35 U.S.C. § 103(a) as being obvious in view of WO 96/20737 (Prévost *et al.*). Claims 72, 73 and 75 were rejected under 35 U.S.C. § 103(a) as being obvious over WO 96/20737 (Prévost *et al.*) in view of Belfer *et al.* (US 6,106,854). Claim 76 was rejected under 35 U.S.C. § 103(a) as being obvious over WO 96/20737 (Prévost *et al.*) in view of Saferstein *et al.* (US 6,086,856) and further in view of Sheiness *et al.* (US 5,776,694). Claim 77 was rejected under 35 U.S.C. § 103(a) as being obvious over Goldemberg *et al.* (US 4,666,708). Claims 41 and 78 were rejected under 35 U.S.C. § 103(a) as being obvious over EPA 0109279 (Willcockson *et al.*) in view of Prévost *et al.* (US 5,731,275).

Claims 51 and 52 have been amended for the purpose of consistency, by adding the term “suitable”. It is respectfully submitted that this amendment is permissible based on the disclosure as originally filed. Claim 80 has been amended to read more clearly. No new matter has been added.

The claims have been amended to recite a two-step method resulting in the decontamination of small diameter water lines. The method comprises a first step of treating the inner surface of the small diameter water lines followed by a second “rinsing” step. Support for

the rinsing step can be found in the specification as originally filed (*i.e.* page 8 lines 12 and 30). No new matter has been added. The rinsing step ensures complete decontamination of the small diameter water lines. The presence of a bactericide is contributory to the present method. The bactericide is added in order to both increase the efficiency and speed of the decontamination process.

Applicants respectfully submit that the present amendments, directed at a two-step method for decontaminating small diameter water lines, overcome the rejections in view of Tuompo *et al.*

Tuompo *et al.* does not teach or suggest the decontamination of small diameter water lines wherein no mechanical action or scrubbing can be practiced. Instead, Tuompo *et al.* studied micro-organisms by delicately removing and growing them in order to discover how they resist decontamination. The best removal conditions, as disclosed by Tuompo *et al.*, uses a solution consisting of 1% SDS in 0.01 M tris-acetate buffer (pH 7.75), 0.07% EDTA and 1% dithiotreitol (see Table 3; the row showing the efficacy of 1.0% SDS). Furthermore, the results illustrated in Table 5 are no better, since the best result (in terms of percentage of biofilm remaining on a surface following 28 days of treatment) is 6.9%, and this is in the presence of a scrubbing agent such as sodium metasilicate. Tuompo *et al.* conclude that: "*the amount of biofilm left on the surface was one tenth of the original amount after spraying with a blend of Triton-X-100, triethanol amine and sodium metasilicate. Spraying on the surface of the biofilm made the removal more efficient, without damaging the bacteria*" (see Column 17, lines 63-67).

Applicants respectfully assert that since Tuompo *et al.* were concerned with the harvesting of micro-organisms, without causing any harm to the micro-organisms, Tuompo *et al.* inherently did not carry out any experiments wherein they could have observed complete decontamination at the risk of damaging the micro-organisms. More specifically, Tuompo *et al.* did not use "an effective biofilm-dislodging amount of a detergent and an effective biofilm-dislodging amount of a salt-forming acid". Applicants have amended claims 41 and 68 by

withdrawing the proviso “or 1% SDS and 0.1% or less EDTA”, since such a small amount of EDTA would not be effective.

Claim rejections for Double Patenting

U.S. Patent No. 6,762,160 (Barbeau *et al.*) is cited as the basis for grounds of rejection for “obviousness-type double patenting”. Applicants submit that the cited patent solely comprises composition claims, in contrast to the presently pending application, which is solely directed to method claims. As Applicants assert that the double patenting rejections are improper and should be withdrawn, Applicants have chosen not to file a terminal disclaimer at this time.

Claim rejections under 35 U.S.C. § 102(b) in view of Goldemberg *et al.* (US 4,666,708).

Applicants submit that the cited reference teaches a dental rinse that is to be applied to the teeth in order to loosen plaque, rendering it more amenable to removal during brushing with a conventional dentifrice. However, the cited reference is silent about the decontamination of small diameter water lines without a mechanical aid. Applicants assert that the rejection is overcome.

Claim rejections under 35 U.S.C. § 102(e) in view of Tuompo *et al.* (US 5,910,420).

As discussed here above, the cited reference does not teach or suggest the decontamination of small diameter water lines wherein no mechanical action or scrubbing can be practiced. The Action states that “*it is not clear that applicant disclaims agents added to the solution*”. It is respectfully submitted that Applicants disclaim only their own compositions. Applicants have discovered that a solution minimally comprising a biofilm-dislodging amount of a detergent and a biofilm-dislodging amount of a salt-forming acid is required to remove a biofilm from a contaminated inner surface with such efficacy that only an additional rinsing step is necessary to achieve decontamination. The presence of a bactericide(s) is optional. It is

respectfully submitted that since no such solution is presently available, the present discovery fulfills a longstanding need.

Applicants respectfully submit that Tuompo *et al.* do not teach or suggest the claimed method of the presently pending application (*i.e.* decontaminating small diameter water lines without mechanical aid). Tuompo *et al.* teach the removal of biofilms without destroying them. The best results obtained by Tuompo *et al.* for removing a biofilm are achieved with compositions that do not comprise effective biofilm-dislodging amounts of salt-forming acids. The low concentrations of salts/acids did not, in adjunction with SDS, achieve complete removal of the biofilm from treated surfaces. Furthermore, these surfaces were not small diameter water lines wherein the use of a mechanical aid cannot be envisaged.

Applicants have amended the presently pending claims by reciting the decontamination of small diameter water lines without the use of a mechanical aid. It is respectfully submitted that in view of such an amendment to the presently pending claims, the exclusion of the compositions taught by Tuompo *et al.* is no longer required. Tuompo *et al.* never “decontaminated” any surface and most certainly did not decontaminate small diameter water lines; the compositions disclosed by Tuompo *et al.* not being composed to perform such a task. Applicants assert that the rejections are traversed.

Claim rejections under 35 U.S.C. § 103(a) in view of WO 96/20737 (Prévost *et al.*)

It was previously requested that Applicants delete the term “about” from the disclaimed ranges. However, the current Action now states that the “*the prior art of record would have expected the results to be achieved at ranges minutely outside the disclosed ranges*” which is what Applicant attempted to claim when making use of the term “about”. Applicants have reintroduced the term “about” in the presently pending set of claims. Applicants respectfully submit that the removal of the term “about” was unduly limiting.

In an effort to understand why the cited compositions performed so well, Applicants discovered other novel and non-obvious compositions provided they comprise an effective biofilm-dislodging amount of a detergent and an effective biofilm-dislodging amount of a salt forming acid. Applicants submit that this finding was unexpected and could not have been predicted on the basis of past work. The presently claimed compositions are efficacious for decontaminating the inner inaccessible lumen of small diameter water lines.

The cited reference discloses three efficient compositions: i) 1% to 2% SDS, 1% EDTA and 5% hydrogen peroxide; ii) 1% to 2% SDS, mandelic and lactic acids (total 2%); and iii) 1% to 2% SDS, 1% EDTA, 5% hydrogen peroxide and mandelic and lactic acids (total 2%). Applicants respectfully submit that compositions comprising from about 1% to about 2% SDS and about 1% EDTA, notwithstanding the presence or absence of a bactericide such as hydrogen peroxide, are disclaimed from the presently pending application. Furthermore, compositions comprising from about 1% to about 2% SDS and mandelic and lactic acids, notwithstanding the presence or absence of other components such as EDTA and hydrogen peroxide, are also disclaimed from the presently pending application. Regarding the present pending claims, the bactericide was not included in the disclaimer since its presence is optional. The simple treatment of a contaminated surface with a composition as disclosed in the presently pending application, followed by rinsing the treated surface, is sufficient for decontaminating small diameter water lines. The presence or lack of a bactericide only provides for increased efficiency

and speed, since less rinsing is required if the bacteria present in the dislodged biofilm are destroyed.

Indeed, a major difference between the invention as disclosed in the presently pending application and Applicants' past work is the unexpected finding that a bactericide is a non-essential component for decontamination. Past work teaches the systematic use of a bactericide to achieve decontamination (*i.e.* complete absence of microbial re-growth). The present invention illustrates that biofilm detachment is possible with a minimal list of components (acids/salts and detergent) followed by rinsing, which flushes the detached biofilm and microbes from the water lines.

With regards to present claims 41 and 43, Applicants submit that even though a detergent (SDS) may be present in an amount of at least 0.1%, the concentration due to the disclaimer should not be from about 1% to 2%. Low concentrations of detergent will only require more time for achieving decontamination. What matters is its combination with a biofilm-dislodging amount of a salt-forming acid to achieve decontamination in whatever time assigned to the task. The range of about 1 to 2% SDS is recited for the sole purpose of excluding Applicants' past compositions. Applicants assert that the claims patentably distinguish over the reference.

Claim rejections under 35 U.S.C. § 103(a) in view of Belfer *et al.* (US 6,106,854) and WO 96/20737 (Prévost *et al.*).

Applicants assert that the cited reference merely teaches pH-modifiers. The teachings by Belfer *et al.* are silent as to specifically selecting fumaric or phosphoric acid as the most performing biofilm removing acid, and to combining the same with EDTA and SDS for the purpose of decontaminating water lines. There is no motivation for a skilled technician in the art to combine the teachings of WO 96/20737 with those by Belfer *et al.* It is respectfully submitted by Applicants that the present selection of salt-forming acids cannot be predicted from either of the cited references. The selection of the salt-forming acids is not for the purpose of pH adjustment. Instead, the salt-forming acids are an active ingredient (biofilm-dislodging agent) in

the compositions as described in the presently pending application for decontaminating small diameter water lines. Applicants assert that the rejection is traversed.

Claim rejections under 35 U.S.C. § 103(a) in view of Saferstein *et al.* (US 6,086,856), Sheiness *et al.* (US 5,776,694) and WO 96/20737 (Prévost *et al.*).

Applicants submit that Saferstein *et al.* are not concerned with decontaminating small diameter water lines comprising a biofilm. It is thus respectfully submitted that there is no motivation to combine the teachings of WO 96/20737 and those by Saferstein *et al.*

Applicants submit that Sheiness *et al.* are concerned only with lysing cells while preserving the integrity of microbial nucleic acids. It is respectfully submitted that this reference does not provide any complementary information to a skilled technician in the art providing the motivation to combine the teachings of WO 96/20737 with those by Sheiness *et al.* to arrive at the presently claimed subject matter. Applicants assert that the rejection is traversed.

Claim rejections under 35 U.S.C. § 103(a) in view of Goldemberg *et al.* (US 4,666,708).

As discussed hereinabove, Applicants submit that the cited reference teaches a dental rinse that is to be applied to the teeth in order to loosen plaque, rendering it more amenable to removal during brushing with a conventional dentifrice. However, the cited reference is silent about the decontamination of small diameter water lines without a mechanical aid. Applicants assert that the rejection is traversed.

Claim rejections under 35 U.S.C. § 103(a) in view EPA 0109279 (Wilcockson *et al.*) and Prévost *et al.* (US 5,731,275).

Applicants submit that the cited references disclose the decontamination of surgical instruments. However, there is silence about decontaminating small diameter water lines without a mechanical aid (*i.e.* scrubbing). It is thus respectfully submitted that there is no motivation to combine the teachings of US 5,731,275 with those by Wilcockson *et al.* (EPA 0109279). Applicants assert that the rejection is traversed.

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Reply to Office Action dated July 9, 2004

In view of the foregoing, it is believed that the rejections of the claims have been overcome by the present remarks and amendments, and that the presently claimed method is original and patentable and is in a condition for allowance.

If the Examiner feels that a telephone interview may be helpful in this matter, please contact Applicants' representative at 612.336.4728.

Respectfully submitted,

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